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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/914,286	08/24/2001	Satoshi Omura	468-30	2354
23117	7590	04/21/2004	EXAMINER	
NIXON & VANDERHYE, PC 1100 N GLEBE ROAD 8TH FLOOR ARLINGTON, VA 22201-4714			NASHED, NASHAAT T	
			ART UNIT	PAPER NUMBER
			1652	

DATE MAILED: 04/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/914,286	Applicant(s) OMURA ET AL.	
	Examiner Nashaat T. Nashed, Ph. D.	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 February 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 16, 31, 32, 34-42 and 44-56 is/are pending in the application.
- 4a) Of the above claim(s) 39-42 and 49-56 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 46-48 is/are allowed.
- 6) ☒ Claim(s) 1, 2, 16, 31, 32, 34-38, 44, and 45 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

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The amendment filed February 9, 2004 have been entered. Accordingly, claims 3-15, 17-30, and 33 have been canceled, claims 1, 2, 16, 31, 32, and 34-40 have been amended, and new claims 44-56 have been entered.

Claims 1, 2, 16, 31, 32, 34-38, and 44-48 are under consideration, and claims 39-42 remain withdrawn from further consideration. New claims 49-56 are directed to the non-elected subject matter of claims 39-42 and non-elected claim 43, now canceled. Thus, new claims 49-56 are also withdrawn from further consideration.

The examiner regret the typographical error of indicating that claim 34 is withdrawn in the prior Office action mailed August 7, 2003. Claim 34, however, was fully examined in the prior Office action.

The restriction has been traversed in the prior Office action mailed August 7, 2003, and the restriction requirement has been made final. The examiner has no further comment to add to the previous argument, and the restriction requirement remains **Final**.

New formal drawings are required in this application because new Figure 2B contain chemical structure wherein single C-C bond is represented by a double line. Such a representation is reserved by convention for double bonds, and thus, the figure is confusing. Applicant is advised to employ the services of a competent patent draftsman outside the Office, as the Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

New Rejection:

35 U.S.C. § 101 reads as follows:

"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title".

Claim 35 is rejected under 35 U.S.C. § 101 because the claimed invention is directed toward non-statutory subject matter. The claim is directed to a transformant, i.e., a transformed organism, which includes man. The ownership of man is repugnant to the vast majority of American. Amending the claim to be limited to "a host cell" would obviate this rejection.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, 16, 31-38 and 44-48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following are the reasons for the rejections:

- (a) The phrase "sequence represented by SEQ ID NO:" in claims 1, 2, 16, 32, and 44 renders the claims indefinite because the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. For examination purposes only, it is assumed that residues 1-11916 of SEQ ID NO: 1 and the amino acid sequence of SEQ ID NO: 3 represent a genus of nucleic acid and amino acid sequences, respectively, which does not limit the claim specific nucleic or amino acid sequence. Substituting the phrase "represented by" with "of" would obviate this rejection.
- (b) The phrase AT' and ACP' in claim 44 render the claims indefinite because the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. The activity of the starter module in SEQ ID NO: 3 are named in the specification ATs and ACPs. There is no AT' and ACP' described in the specification. For examination purposes only, it is assumed that the applicants intended to say ATs and ACPs.
- (c) Claim 44 is indefinite because the hybridization conditions represent various ranges of reagent and does not cite a specific hybridization conditions. For examination purposes only, it is assumed any hybridization conditions at 65 degree C.
- (d) Claim 31, 34-38, and 45-48 is included in these rejection because they are dependent on rejected claims and do not cure its deficiencies.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 34-36 and 44 are rejected under 35 U.S.C. 102(b) as being anticipated by Gewain *et al.* [U. S. Patent 5,262,474 (474')].

In response to the above rejection, applicant traverse the rejection based on the ground that the 474' patent does not teach any nucleotide sequence.

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Applicant's arguments filed 2/9/04 have been fully considered but they are not persuasive. The examiner agrees that the 474' patent does not teach nucleic acid sequence. Applicants' attention is directed to the fact that the claimed invention is not directed to a nucleic acid sequence. It is directed to a nucleic acid molecule comprising a nucleic acid sequence represented by residues 1-11916 of SEQ ID NO: 1. The claims are not limit to any specific nucleic acid sequence because the phrase "represented by" expand the claim to include any nucleic acid sequence, which encode similar activity. The 474' patent indeed teaches a nucleic acid molecule, having an identical function and nearly identical sequence. Applicant should be reminded that the sequence is an intrinsic property of a nucleic acid molecule, and similar to any other properties the molecule have such as electrophoretic mobility on a gel and the polypeptide which encoding.

Regarding new claim 44, since the nucleic acid molecule disclosed in the 474' patent is isolated from the same species and encoding the same enzymatic activity, it would be expected to hybridize to the nucleic acid of residues 1-11916 of SEQ ID NO: 1 under any hybridization conditions.

The following is a quotation of 35 U.S.C. 103, which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103.

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Claims 1, 2, 34-37 and 44 and are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103 as obvious over Gewain *et al.* [U. S. Patent 5,262,474 (474')].

In response to the above rejection, applicant traverse the rejection based on the ground that the 474' patent does not teach any nucleotide sequence, and it is difficult to determine a nucleic acid sequence with high GC content. In addition, it would be difficult to determine the domain structure of the gene cluster.

Applicant's arguments filed 2/9/04 have been fully considered but they are not persuasive. The examiner agrees that the 474' patent does not teach nucleic acid sequence. Applicants contend that it is difficult to sequence a nucleic acid sequence with a high GC content such as that of *Streptomyces avermitis*, and therefore, presumably, their effort should be rewarded with a patent. Applicants' attention is directed to the fact that the claimed invention is not directed to a nucleic acid sequence or a method of sequencing nucleic acid having high GC content. The claimed invention is directed to a nucleic acid molecule, vector, and host cell, which have been described in the prior art of record. While it may be difficult, expensive, and time consuming to sequence a known gene cluster such as that from *S. avermitis*, it was within the skill of one of ordinary skilled in the art to sequence the gene cluster and determine its domain structure.

These rejections are being made under 35 U.S.C. 102(b) and 35 U.S.C. 103 because it is not possible for the Examiner to physically compare the claimed nucleic acid sequences encoding the polyketide synthase of SEQ ID NO: 3 and fragments thereof; or those that hybridized to said nucleic acid under any hybridization conditions to those taught in the 474 patent. Applicant bears the burden of providing evidence, which distinguishes the claimed nucleic acid sequences of the instant application and those disclosed in the 474 patent. A preferred means of providing this evidence is for applicant to submit a side-by-side comparison between the claimed nucleic acid sequences of the instant application and that of the 747 patent which demonstrates any material differences and shows the claimed nucleic acid encoding the polyketide synthase of SEQ ID NO: 3 to be distinct and unobvious in view of the enzymes of the prior art. *In re Best, Bolton, and Shaw* 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald, Sanders and Bagheri* 205 USPQ 594 (CCPA 1980).

Claims 46-48 are allowed.

Claim 16, 32, and 45 would be allowable, if they are amended to overcome the rejections made under 35 U. S. C. 112, second paragraph.

Claim 2 would be allowable, if it is amended to overcome the rejections made under 35 U. S. C. 112, second paragraph, and the word "comprises" at the end of line 2 of the claim is replaced with -----consisting of-----.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nashaat T. Nashed, Ph. D. whose telephone number is 571-272-0934. The examiner can normally be reached on MTTF.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Nashaat T. Nashed, Ph. D.
Primary Examiner
Art Unit 1652